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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
[illegible]	
ART UNIT	**PAPER NUMBER**
1644	10

DATE MAILED: [illegible]

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Office Action Summary	Application No. 09/257,188	Applicant(s) Glenn et al.
	Examiner G. R. Ewoldt	Group Art Unit 1644

X Responsive to communication(s) filed on *Jan 16, 2001*.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-59* is/are pending in the application.

Of the above, claim(s) _____ *is/are withdrawn from consideration.*

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

X Claims *1-59* are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ *is/are objected to by the Examiner.*

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election of Group III, Claims 1-37, 39-46, 50-51, 55, and 57 and the adjuvant species ADP-ribosylating exotoxin in Paper No. 9, filed 1/16/01, is acknowledged. Upon further consideration an additional species election is required. The previous restriction requirement and election are therefore vacated. A new restriction follows. The Examiner apologizes for any delay or inconvenience to the Applicant.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-34, 36-37, 39-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a tumor antigen, classified in Class 424, subclasses 277.1, 278.1 and 283.1.

II. Claims 1-34, 37, 39-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to an antigen derived from a normal cell, classified in Class 424, subclasses 278.1 and 283.1.

III. Claims 1-37, 39-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a bacterial antigen, classified in Class 424, subclasses 234.1, 278.1 and 283.1.

IV. Claims 1-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a viral antigen, classified in Class 424, subclasses 204.1, 278.1 and 283.1.

V. Claims 1-37, 39-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a fungal antigen, classified in Class 424, subclasses 278.1 and 283.1.

VI. Claims 1-37, 39-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a parasite, classified in Class 424, subclasses 265.1, 278.1 and 283.1.

VII. Claims 1-37, 39-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to an autoantigen, classified in Class 424, subclasses 278.1 and 283.1.

VIII. Claims 1-37, 39-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to an allergen, classified in Class 424, subclasses 275.1, 278.1 and 283.1.

IX. Claims 1-34, 36, 39-49, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a tumor antigen encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

X. Claims 1-34, 39-49, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to an antigen derived from a normal cell encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

XI. Claims 1-36, 39-49, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a bacterial antigen encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44..

XII. Claims 1-36, 39-46, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a viral antigen encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

XIII. Claims 1-36, 39-49, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a fungal antigen encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

XIV. Claims 1-36, 39-49, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to a parasite encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

XV. Claims 1-36, 39-49, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to an autoantigen encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

XVI. Claims 1-36, 39-49, 50-51, 55, and 57, drawn to a method of inducing an enhanced immune response to an allergen encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

XVII. Claims 52-54, drawn to an article for vaccine administration, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

XVIII. Claim 56, drawn to a method of preventing a disease, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

XIX. Claims 58-59, drawn to a composition, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

The inventions are distinct, each from the other because:

3. Inventions I-XVI and XVIII are different methods. These inventions require different reagents acting through different process steps, with different modes of operation, different endpoints, and/or different outcomes. Therefore they are patentably distinct.

4. Inventions XVII and XIX are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a vaccine and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Inventions XIX and (I-XVI and XVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in *in vitro* assays.

6. Because these inventions are distinct for the reasons given above and Groups I-XIX have acquired a separate status in the art as shown by their different classification and/or the searches are not co-extensive and because the Groups encompass divergent subject matter, restriction for examination purposes as indicated is proper.

7. Should Applicant elect any of Groups I-XVI, Applicant is further required under 35 U.S.C. § 121 to elect a **specific** method of pretreatment comprising:

A) a **specific** adjuvant, such as one listed in Claims 22 or 44-46,

B) a **specific** "enhancer", such as alcohol, acetone, a detergent, a salicylate, or a "surface disrupting device".

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different adjuvants, such as cholera toxin or chemokines, elicit different immune responses of different classes. The different enhancers, such as a detergent and a surface disrupting device, enhance the penetration of an antigen and adjuvant in different ways, i.e., chemical versus mechanical. Therefore, the species of Groups I-XVI are independent and patentable over one another.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Applicant is advised that no references were received with the IDS form PTO-1449, received 12/09/99. Submission or resubmission of said references would expedite prosecution.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail

service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
March 19, 2001

Patrick J. Nolan, Ph.D.
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